



It's not too late to  
vaccinate against HPV

**START THE  
DISCUSSION**



**GARDASIL® 9**

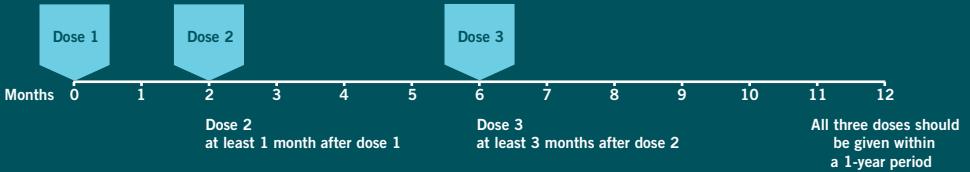
[Human Papillomavirus  
9-valent Vaccine, Recombinant]



# DOSING GUIDE

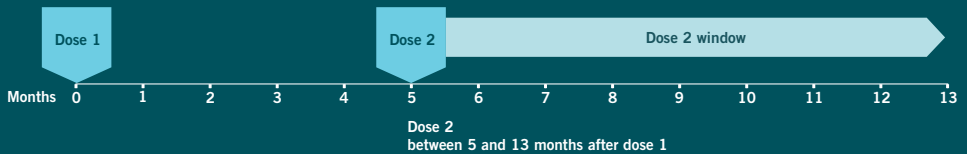
## Schedule for individuals 15 years of age and older<sup>1</sup>

### 3-dose schedule:



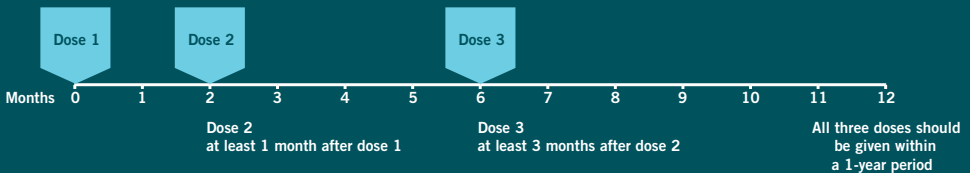
## Schedule for individuals aged 9–14 years of age<sup>1</sup>

### 2-dose schedule:



If the individual is immunocompromised or the second dose is administered earlier than 5 months, then a third dose will be required.

### 3-dose schedule:



---

THIS BOOKLET IS DESIGNED TO HELP YOU:

1. IDENTIFY ELIGIBLE PATIENTS
2. START THE CONVERSATION
3. PROVIDE ANSWERS



# 1. IDENTIFY ELIGIBLE PATIENTS

In 2019, Gardasil 9 was introduced into the national vaccination schedule for boys and girls in first year of secondary school to prevent infection from the most prevalent HPV types that are responsible for 90% of HPV-related cancer.<sup>2</sup> HPV vaccination is also offered to men and women infected with HIV up to and including 26 years of age, and for men who have sex with men (MSM), including MSM infected with HIV, up to and including 45 years of age.<sup>2</sup> Gardasil 9 is the vaccine of choice used within the National Immunisation Programme and is also available privately for non-funded vaccination.

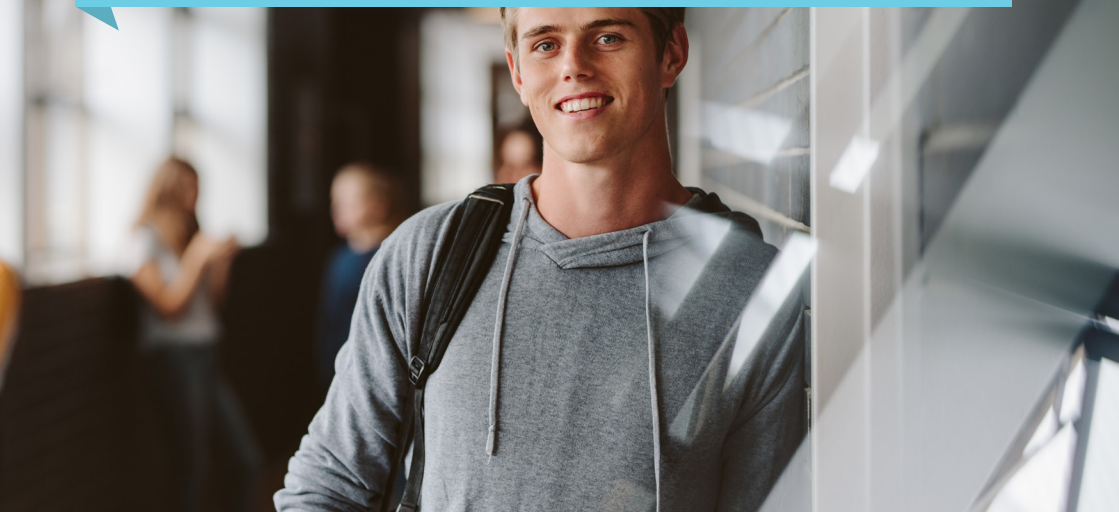
Gardasil 9 is indicated for active immunisation of individuals from the age of 9 years against the following HPV diseases:<sup>1</sup>

- Premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccine HPV types.
- Genital warts caused by specific HPV types. There is no upper age limit.

**An estimated 80% of sexually active men and women become infected with at least one type of HPV by age 50 years<sup>2</sup>**

- HPV is the most common sexually transmitted infection worldwide.<sup>3</sup>
- Most HPV infections occur without symptoms and resolve without treatment because your body can clear the virus itself.<sup>2,4</sup>
- But for others, who don't clear the virus, HPV infection can develop into cancer or genital warts.<sup>4</sup>

***Pro Tip # 1: Your recommendation is the most important factor in a person's decision to vaccinate<sup>5</sup>***





# Persistent HPV infection can lead to several HPV-related cancers and diseases in men and women<sup>3</sup>

Annual Incidence of HPV related cancers in Ireland in 2020<sup>6</sup>

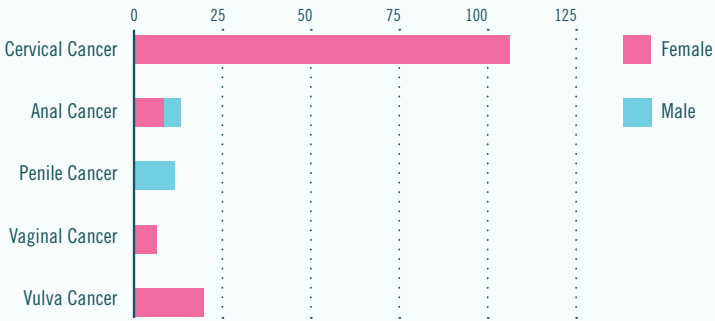
<b>Penile Cancer</b>	<b>39</b>
<b>Anal Cancer</b>	<b>62</b>
<b>Vulvar Cancer</b>	<b>60</b>
<b>Vaginal Cancer</b>	<b>13</b>
<b>Cervical Cancer</b>	<b>342</b>



# Why prevention matters

Each year in Ireland there is a significant number of people who die from HPV related cancers.<sup>6</sup>

**Annual Incidence of HPV-related cancer mortality in Ireland in 2020<sup>6</sup>**

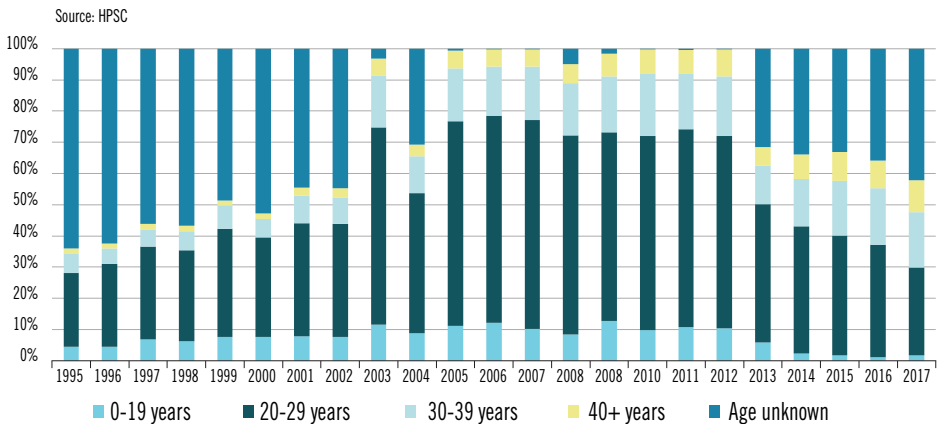


**This is why HPV vaccination is more important than ever.**

# HPV does not discriminate. If you are sexually active, you can get HPV<sup>3</sup>

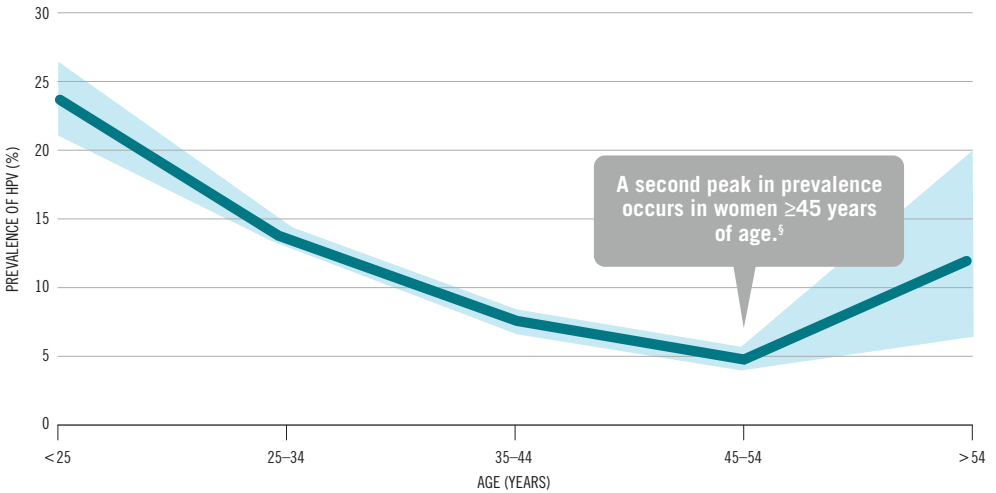
While anogenital warts are notifiable in Ireland, there is significant under-reporting. In 2018, there were 1,031 anogenital wart notifications.<sup>7</sup>

**Percentage of anogenital warts by age group in Ireland 1995-2017<sup>2</sup>**



# Many adult males and females continue to be at risk of acquiring new HPV infections throughout their lifetime<sup>8</sup>

HPV prevalence by age among women with normal cytology in Europe<sup>9\*</sup>



\*countries include Russia, Denmark, Sweden, UK, Greece, Italy, Spain, Belgium, France, Germany and Netherlands

**Pro Tip # 2:** Many adult males and females continue to be at risk of acquiring new HPV infections throughout their lifetime<sup>8</sup>

## 2. START THE CONVERSATION

### Because your patients won't always bring it up with you!

- Your recommendation is the most important factor in a person's decision to vaccinate<sup>5</sup>

### There are many opportunities to discuss HPV vaccination, for example:

- Routine checkups
- Recent change in relationship status
- Routine immunizations or travel vaccinations
- HPV screenings
- Contraception-related visits
- Sexual health/STI-related discussions
- Prior HPV infection or genital wart consultations
- Colposcopy visits/Post Colposcopy treatment

**YOU HAVE THE POWER** to help prevent certain HPV-related cancers and diseases.<sup>5</sup>

### Conversation starters

"I strongly recommend this vaccine to help protect you from cervical cancer and other HPV-related cancers and diseases."<sup>3</sup>

---

"Have you had the HPV vaccine? Did you know approximately **80% of sexually active men and women become infected with at least one type of HPV by age 50 years?**<sup>2</sup> While most people clear the virus, those who don't can develop HPV-related cancers or genital warts."<sup>3</sup>



# Reinforce the importance of vaccination

Worldwide estimated type contribution for certain HPV-related cancer and disease cases<sup>2,4</sup>

	<b>9 HPV types</b> 6 11 16 18 31 33 45 52 58 cause a total of:
Cervical cancer cases <sup>†</sup>	<b>90%</b>
Cervical precancerous lesions <sup>†</sup>	<b>75–85%</b>
Low-grade cervical lesions <sup>†</sup>	<b>50–60%</b>
HPV-related vulvar cancer cases <sup>†</sup>	<b>85–90%</b>
HPV-related vaginal cancer cases <sup>†</sup>	<b>80–85%</b>
HPV-related anal cancer cases <sup>†</sup>	<b>90–95%</b>
Genital warts cases	<b>90%</b>

Adapted from NIAC Guidelines. Available at <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter10.pdf>

# 3. PROVIDE ANSWERS TO COMMON QUESTIONS

**Q. Can I still get the HPV vaccine at my age?**

**A.** GARDASIL9 is indicated for active immunisation of individuals from the age of 9 years.<sup>1</sup> There is no upper age limit.<sup>1</sup>

**Q. Is there a benefit in HPV vaccination post CIN2+/CIN3+ treatment?**

**A.** HPV Vaccination post CIN2+/CIN3+ treatment has been shown to significantly reduce the development of new lesions and recurrent disease.<sup>11</sup> Over 6,500 women in Ireland need hospital treatment for pre-cancer of the cervix.<sup>4</sup> These women would all benefit from HPV vaccination post treatment.<sup>11</sup>

**Q. Will GARDASIL9 still help me if I've already had HPV?**

**A.** Even if you've already had an HPV infection, you can still receive HPV vaccination.<sup>2</sup> If you're already infected with one type of HPV contained in the vaccine, GARDASIL<sup>®</sup>9 will help protect you against the other 8 types.<sup>1</sup> The vaccine cannot treat an existing HPV infection, however.<sup>1</sup>

**Q. Is there a benefit in vaccinating older men and women with Gardasil 9?**

**A.** Men and women continue to be at risk of HPV infections throughout their lifetime.<sup>8</sup> Although new HPV infections are most commonly acquired in adolescence and young adults, some adults are at risk for acquiring new HPV infections.<sup>8</sup> At any age, having a new sex partner is a risk factor for acquiring a new HPV infection.<sup>8</sup> Older men and women could benefit from vaccination with Gardasil 9 because if you don't have an HPV infection the vaccine will protect you against 9 types of HPV that can lead to genital warts and certain HPV related cancers.<sup>1</sup> However, even if you already have an HPV infection the vaccine will protect you from getting other types of HPV infections.<sup>8</sup>

**Q. If I am a female and get vaccinated with GARDASIL9, do I still need to get regular screenings?**

**A.** GARDASIL9 vaccination will help protect you against 9 strains of HPV<sup>1</sup>. Vaccination does not remove the need for cervical cancer screening.<sup>1</sup> Even if you have had the HPV vaccine, you should have your cervical screening test (smear test) each time it's due.<sup>1,4</sup> This is because the HPV vaccine doesn't give complete protection against cervical cancer.<sup>4,8</sup> Early detection and management of cervical dysplasia has been shown to have an impact on cervical cancer incidence and outcome.<sup>2</sup> GARDASIL9 is not indicated to manage and/or treat cervical cancer or dysplasia.<sup>1</sup>

**Q. Is it too late to get vaccinated if I'm already sexually active?**

**A.** It may not be too late to help protect yourself against HPV. And if you're already infected with one type of the virus, it might not be too late to help protect yourself against other types of HPV you haven't been exposed to.<sup>8,10</sup>

**Q. Why should I get vaccinated if I only have one sexual partner?**

**A.** GARDASIL9 vaccination can help protect you in the event that you have a change in sexual partners one day.<sup>3,8</sup> You can be at risk even if you have only one sexual partner because your partner may have had other partners in the past.<sup>3,8</sup> HPV is a common virus. Without vaccination, the majority of sexually active people will catch HPV during their lifetime.<sup>3,8</sup> Many people who have HPV may not show any signs or symptoms. This means that they can transmit (pass on) the virus to others without knowing it.<sup>3,8</sup> Each partner in a sexual relationship may carry the infection for many years without knowing it because there are often no visible symptoms.<sup>3,8</sup>

**Q. Since our last discussion, I've had a change in relationship status, how can GARDASIL9 help me?**

**A.** A change in sexual behaviour or sexual partners is a risk factor for HPV.<sup>8</sup>

**Q. Is GARDASIL9 covered by insurance?**

**A.** You may have private health insurance that partly covers vaccination with GARDASIL9. Speak to your insurance company directly.

**Q. Where can I get the Gardasil 9 vaccine?**

**A.** You will need a prescription from your GP or nurse to get the Gardasil 9 vaccine. Some pharmacies such as Llyod's and Boots offer an online HPV vaccination consultation to get the prescription. Once you have the prescription you can get the vaccine in your GP or in selected pharmacies across Ireland.

**Q. What is the dosing schedule for Gardasil 9?**

**A.**

AGE	DOSAGE	ADMINISTRATION
9 through 14 years (males & Females)	2-dose	0, 5 to 13 months
	3-dose	0, 2, 6 months
≥ 15 years (males & Females)	3-dose	0, 2, 6 months

# Help protect you eligible male and female patients with Gardasil 9

Recommend Gardasil 9 to prevent future infections against 9 of the most common high risk HPV types.

To order Gardasil 9  
Phone: 1800 200 845  
Email: [msd@united-drug.com](mailto:msd@united-drug.com)

## Recommended schedule for GARDASIL 9<sup>1</sup>

AGE	DOSAGE	ADMINISTRATION
9 through 14 years (males & Females)	2-dose	0, 5 to 13 months
	3-dose	0, 2, 6 months
≥ 15 years (males & Females)	3-dose	0, 2, 6 months

### GARDASIL® 9 (Human Papillomavirus 9-valent Vaccine (Recombinant, adsorbed)).

**ABRIDGED PRODUCT INFORMATION** Refer to Summary of Product Characteristics before prescribing. **PRESENTATION** Gardasil 9 is supplied as a single dose pre-filled syringe containing 0.5 millilitre of suspension. Each dose of vaccine contains highly purified virus-like particles (VLPs) of the major capsid L1 protein of Human Papillomavirus (HPV). These are type 6 (30 µg), type 11 (40 µg), type 16 (60 µg), type 18 (40 µg), type 31 (20 µg), type 33 (20 µg), type 45 (20 µg), type 52 (20 µg) and type 58 (20 µg). **INDICATIONS** Gardasil 9 is a vaccine for use from the age of 9 years for the prevention of premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccine HPV-types and genital warts (condyloma acuminata) caused by specific HPV types. The indication is based on the demonstration of efficacy of Gardasil 9 in males and females 16 to 26 years of age and on the demonstration of immunogenicity of Gardasil 9 in children and adolescents aged 9 to 15 years. The use of Gardasil 9 should be in accordance with official recommendations.

**DOSAGE AND ADMINISTRATION** *Individuals 9 to and including 14 years of age at time of first injection:* Gardasil 9 can be administered according to a 2-dose schedule. The second dose should be administered between 5 and 13 months after the first dose. If the second vaccine dose is administered earlier than 5 months after the first dose, a third dose should always be administered. Gardasil 9 can be administered according to a 3-dose (0, 2, 6 months) schedule. The second dose should be administered at least one month after the first dose and the third dose should be administered at least 3 months after the second dose. All three doses should be given within a 1-year period. *Individuals 15 years of age and older at time of first injection:* Gardasil 9 should be administered according to a 3-dose (0, 2, 6 months) schedule. The second dose should be administered at least one month after the first dose and the third dose should be administered at least 3 months after the second dose. All three doses should be given within a 1-year period. It is recommended that individuals who receive a first dose of Gardasil 9 complete the vaccination course with Gardasil 9. The need for a booster dose has not been established. Studies using a mixed regimen (interchangeability of HPV vaccines) were not performed for Gardasil 9. Subjects previously vaccinated with a 3 dose regimen of quadrivalent HPV types 6, 11, 16, and 18 vaccine (Gardasil or Silgard), hereafter referred to as qHPV vaccine, may receive 3 doses of Gardasil 9. The use of Gardasil 9 should be in accordance with official recommendations. *Paediatric population (children <9 years of age):* The safety and efficacy of Gardasil 9 in children below 9 years of age have not been established. No data are available. The vaccine should be administered by intramuscular injection. The preferred site is the deltoid area of the upper arm or in the higher anterolateral area of the thigh. Gardasil 9 must not be injected intravascularly, subcutaneously or intradermally. The vaccine should not be mixed in the same syringe with any other vaccines and substances. **CONTRAINDICATIONS** Hypersensitivity to any component of the vaccine including active substances and/or excipients. Individuals with hypersensitivity after previous administration of Gardasil 9 or Gardasil/Silgard should not receive Gardasil 9. **PRECAUTIONS AND WARNINGS** In order to improve traceability of biological medicinal products, the name and batch number of the administered product should be clearly recorded. The decision to vaccinate an individual should take into account the risk for previous HPV exposure and potential benefit from vaccination. As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine. The vaccine should be given with caution to individuals with thrombocytopenia or any coagulation disorder because bleeding may occur following an intramuscular administration in these individuals. Syncope, sometimes associated with fainting, can occur before or after vaccination with Gardasil 9 as a psychogenic response to the needle injection. Vaccines should be observed for approximately 15 minutes after vaccination; procedures should be in place to avoid injury from faints. Vaccination should be postponed in individuals suffering from an acute severe febrile illness. However, the presence of a minor infection, such as a mild upper respiratory tract infection or low-grade fever, is not a contraindication for immunisation. As with any vaccine, vaccination with Gardasil 9 may not result in protection in all vaccine recipients. Gardasil 9 will only protect against diseases that are caused by HPV types targeted by the vaccine. The vaccine is for prophylactic use only and has no effect on active HPV infections or established clinical disease. The vaccine has not been shown to have a therapeutic effect and is not indicated for treatment of cervical, vulvar, vaginal and anal cancer, high-grade cervical, vulvar, vaginal and anal dysplastic lesions or genital warts. It is also not intended to prevent progression of other established HPV-related lesions. Gardasil 9 does not prevent lesions due to a vaccine HPV type in individuals infected with

that HPV type at the time of vaccination. Vaccination is not a substitute for routine cervical screening. There are no data on the use of Gardasil 9 in individuals with impaired immune responsiveness. Safety and immunogenicity of a qHPV vaccine have been assessed in individuals aged from 7 to 12 years who are known to be infected with human immunodeficiency virus (HIV). Individuals with impaired immune responsiveness, due to either the use of potent immunosuppressive therapy, a genetic defect, Human Immunodeficiency Virus (HIV) infection, or other causes, may not respond to Gardasil 9. Long-term follow-up studies are currently ongoing to determine the duration of protection. There are no safety, immunogenicity or efficacy data to support interchangeability of Gardasil 9 with bivalent or quadrivalent HPV vaccines. **FERTILITY, PREGNANCY AND LACTATION** There are insufficient data to recommend use of Gardasil 9 during pregnancy; therefore vaccination should be postponed until after completion of pregnancy. The vaccine can be given to breastfeeding women. No human data on the effect of Gardasil 9 on fertility are available. **SIDE EFFECTS** Very common side effects include: erythema, pain and swelling at the injection site and headache. Common side effects include: pruritus and bruising at the injection site, dizziness, nausea, pyrexia and fatigue. The post-marketing safety experience with qHPV vaccine is relevant to Gardasil 9 since the vaccines contain L1 HPV proteins of 4 of the same HPV types. The following adverse experiences have been spontaneously reported during post-approval use of qHPV vaccine: urticaria, bronchospasm, idiopathic thrombocytopenic purpura, acute disseminated encephalomyelitis, Guillain-Barré Syndrome and hypersensitivity reactions, including anaphylactic/anaphylactoid reactions. For a complete list of undesirable effects please refer to the Summary of Product Characteristics. **PACKAGE QUANTITIES** Single pack containing one 0.5 millilitre dose pre-filled syringe with two separate needles. **Legal category:** POM Marketing authorisation number: EU/1/15/1007/002 (pre-filled syringe with two separate needles). **Marketing Authorisation holder:** Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands. **Date of revision:** March 2023. © 2023 Merck & Co., Inc., Rahway, NJ, USA and its affiliates. All rights reserved. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin D18 X5K7 or from [www.medicines.ie](http://www.medicines.ie). PSUR PSUSA/00010389/202206

Adverse events should be reported.  
Reporting forms and information can be found at [www.hpra.ie](http://www.hpra.ie)  
Adverse events should also be reported to MSD (Tel: 01-299 8700)

### References

1. Gardasil 9 suspension for injection in a pre-filled syringe | SPC | Medicines.ie [Date of Revision May 2023]. 2. NIAC Immunisation Guidelines. Chapter 10. Human papillomavirus | Royal College of Physicians of Ireland ([preservice.com](http://preservice.com)) [Accessed June 2023]. 3. STD Facts - Human papillomavirus (HPV) (cdc.gov) [Accessed June 2023]. 4. About HPV - HSE. (Accessed June 2023). 5. Paterson, P. et al. (2016) "Vaccine hesitancy and healthcare providers," *Vaccina*, 34(52), pp. 6700-6706. 6. <https://hvcentre.net/statistics/reports/JRLL.pdf?r=1682437410994> [Accessed June 2023]. 7. Ana-Genital Warts - Health Protection Surveillance Centre (hpsc.ie) [Accessed June 2023]. 8. <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hpv.pdf> [Accessed June 2023]. 9. de Sanjosé, S. et al. (2007) "Worldwide prevalence and genotype distribution of cervical human papillomavirus DNA in women with normal cytology: A meta-analysis," *The Lancet Infectious Diseases*, 7(7), pp. 453-459. 10. Mettes, E. et al. (2019) "Human papillomavirus vaccination for adults: Updated recommendations of the Advisory Committee on Immunization Practices," *MMWR. Morbidity and Mortality Weekly Report*, 68(32), pp. 698-702. 11. Jentschke, M. et al. (2020) "Prophylactic HPV vaccination after contraception: A systematic review and meta-analysis," *Vaccine*, 38(41), pp. 6402-6409.



Red Oak North, South County Business Park,  
Leopardstown, Dublin D18 X5K7, Ireland

© 2023 MSD. All rights reserved. The name and logo of MSD are registered trademarks of Merck & Co., Inc. in the USA and other countries. The name and logo of Gardasil 9 are registered trademarks of Merck Sharp & Dohme B.V. in the USA and other countries. The name and logo of Gardasil are registered trademarks of Merck Sharp & Dohme B.V. in the USA and other countries. The name and logo of Silgard are registered trademarks of Merck Sharp & Dohme B.V. in the USA and other countries. The name and logo of Gardasil 9 are registered trademarks of Merck Sharp & Dohme B.V. in the USA and other countries. The name and logo of Gardasil are registered trademarks of Merck Sharp & Dohme B.V. in the USA and other countries. The name and logo of Silgard are registered trademarks of Merck Sharp & Dohme B.V. in the USA and other countries.